UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,900	04/30/2007	Ralph Wirtz	2004P56021US	6097

28524 7590 01/13/2009

SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
170 WOOD AVENUE SOUTH
ISELIN, NJ 08830

EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	**PAPER NUMBER**
1642	

MAIL DATE	DELIVERY MODE
01/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,900	WIRTZ ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-9* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group A, claim(s) 1-6, 8-9, drawn to a kit comprising SEQ ID NOs: 2 and 3, and a method for predicting response to an antibody treatment of breast cancer, using said two markers.

Group B, claim(s) 1-6, 8, drawn to a method for predicting response to an antibody treatment of ovarian cancer, gastric cancer, colon cancer, esophageal cancer, mesenehymal cancer, bladder cancer or non-small cell lung cancer, using SEQ ID NOs: 2 and 3. A method for predicting response to each cancer constitutes a single, distinct invention.

Group C, claims 1-6, 8, drawn to a method for predicting response to an anti-hormonal treatment, anti-growth factor treatment, taxol based treatment, anthraeyelin based treatment or platinum salt based treatment of breast cancer, ovarian cancer, gastric cancer, colon cancer, esophageal cancer, mesenehymal cancer, bladder cancer or non-small cell lung cancer, using SEQ ID NOs: 2 and 3. A method for predicting response to each type of treatment for each cancer constitutes a single, distinct invention.

Group D, claims 1-6, 8, drawn to a method for predicting response to an antibody treatment, anti-hormonal treatment, anti-growth factor treatment, taxol based treatment, anthraeyelin based treatment or platinum salt based treatment of breast cancer, ovarian cancer, gastric cancer, colon cancer, esophageal cancer, mesenehymal cancer, bladder cancer or non-small cell lung cancer, using any combination of genes, genomic sequences, or the specific protein or nucleic acid sequences of a receptor or ligand; or of members of the same signal transduction pathway; or members of synergistic signal transduction pathways; or members of antagonistic signal transduction pathways; or transcription factor and transcription factor binding site; or integral parts of heteromeric complexes cited in claim 4, or a combination of protein or nucleic acid sequences cited in claim 8, which combination is different from the combination of SEQ ID NOs: 2 and 3. A method for predicting response to each type of treatment for each cancer, using each combination of either genes, genomic sequences or proteins constitutes a single, distinct invention.

Group E, claim 7, drawn to a method for prognosis or predicting of breast cancer, ovarian cancer, gastric cancer, colon cancer, esophageal cancer, mesenehymal cancer, bladder cancer or non-small cell lung cancer, using a single nucleic acid or protein recited in claim 7, or a combination thereof. A method for prognosis or predicting each cancer, using each protein or nucleic acid or each combination of either nucleic acids or proteins constitutes a single, distinct invention.

Group F, claim 7, drawn to a method for diagnosis of breast cancer, ovarian cancer, gastric cancer, colon cancer, esophageal cancer, mesenehymal cancer, bladder cancer or non-small cell lung cancer, using a single nucleic acid or protein recited in claim 7, or a combination

thereof. A method for diagnosis of each cancer, using each protein or nucleic acid or each combination of either nucleic acids or proteins constitutes a single, distinct invention.

Group G, claim 9, drawn to a kit comprising a single nucleic acid or protein, or a combination of nucleic acids, which is different from a combination of SEQ ID NOs:2 and 3, or a combination of proteins, as recited in claims 1-8. Each nucleic acid or protein, or each combination of nucleic acids, which is different from a combination of SEQ ID NOs:2 and 3, or each combination of proteins constitutes a single, distinct invention.

This application contains claims of groups A-B, and D directed to the following patentably distinct **species:**

An antibody, which is Herceptin-TM, trastuzumab or C24 antibody.

The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as

the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group A, claims 1-6, 8-9, forms a single general inventive concept.

Groups B-C are additional use of the combination of SEQ ID NOs: 2 and 3.

Groups D-F do not share the same technical feature of group A, because the methods of groups D-F do not use the combination of SEQ ID NO:2 and 3 of group A.

Group G does not share the same technical feature of group A, because the composition of group G do not share a common structure with the combination of SEQ ID NO:2 and 3 of group A.

Further, the inventions within each of groups B-F are not linked by the same technical feature, because the different types of treatment or different target cancers do not share the same properties and characteristics. Similarly, the inventions within each of groups D-G are not linked by the same technical feature, because different proteins or nucleic acids or combination thereof do not share the same structure.

The species antibodies are independent and distinct because different antibodies do not share the same structure and properties.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted, even though the requirement be traversed (37 CFR 1.143). If a genomic sequence were elected, applicants are require to **identify the chromosome region** corresponding to the elected genomic sequence.

If any one of the inventions of groups A-B, D was elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits, and a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
January 09, 2008

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643